DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 6 2007

Re: Symbicort Inhalation Aerosol
Docket No. 2007E-0440

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,674,860 filed by AstraZeneca AB under 35 U.S.C. § 156. The human drug product claimed by the patent is Symbicort Inhalation Aerosol (formoterol fumarate dihydrate and budesonide), which was assigned new drug application (NDA) No. 21-929.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4).

However, our records also indicate that the marketing of the combination product, Symbicort Inhalation Aerosol (formoterol fumarate dihydrate and budesonide), under NDA 21-929 does not represent the first permitted commercial marketing or use of either of the active ingredients in this "product." For purposes of patent term extension in relation to new drug approval, "product" is defined under 35 U.S.C. § 156(f)(2) as "the active ingredient . . . including any salt or ester of the active ingredient. . . ." FDA has previously approved several new drugs containing formoterol fumarate or budesonide. These new drugs include Novartis Pharmaceuticals' Foradil and Dey LP's Perforomist with the active ingredient of formoterol fumarate, and AstraZeneca's Entocort EC, Pulmicort, and Rhinocort with budesonide as the active ingredient.

Patent term extension is not available in connection with an NDA approval if the first permitted commercial marketing or use of the "product" occurred under a previously approved NDA. We concur therefore, in your conclusion that the U.S. Patent No. 5,674,860 is ineligible for patent term extension under 35 U.S.C. § 156, because the components of the product have been previously approved as a human drug under 21 U.S.C. § 355. *See* 35 U.S.C. § 156(a)(5), (f)(2); *see also Fisons Plc v. Quigg*, 876 F.2d 99 (D.C. Cir. 1989); *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990); *Pfizer, Inc. v. Dr. Reddy's Labs.*, 359 F.3d 1361 (Fed. Cir. 2004).

Further, we note that the NDA was approved on July 21, 2006, which makes the submission of the patent term extension application on September 19, 2006, NOT timely within the meaning of 35 U.S.C. § 156(d)(1).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Leslie Morioka, Esq.
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